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Nicaragua

Biotechnology

Annual Report

2007

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Report Highlights:
Nicaragua is implementing the provisions of the Cartagena Protocol. The GON requires a risk analysis for the import of biotechnology products. The risk analysis has not stopped trade between the United States and Nicaragua.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
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SECTION I EXECUTIVE SUMMARY

Yellow corn for animal feed is the main biotechnology crop exported from the United States to Nicaragua. The GON is implementing the provisions of the Cartagena Protocol. It requires notifications of imports of biotechnology products and risk analysis for such imports. The Commission for Risk Analysis of Genetically Modified Organisms (CONARGEN) has performed risk analyses on all genetic events approved by United States for yellow corn destined for processing and feed uses. Yellow corn imports from the United States have continued without delays. The Ministry of Agriculture and Forestry makes biotechnology import requirements available to the public upon request.

SECTION II BIOTECHNOLOGY TRADE AND PRODUCTION

Nicaragua does not produce any biotechnology crops. It does not have the technical resources to develop them for commercial purposes and has not imported biotechnology seeds for planting. Nicaragua is a large food aid recipient due to its limited capacity to supply food for human and animal consumption. Yellow corn for animal feed is the only biotechnology crop imported from the United States. Imports of other biotechnology products from other countries are limited or non-existent.

SECTION III BIOTECHNOLOGY POLICY

Nicaragua is a signatory of the Cartagena Protocol. As part of the process to implement the provisions of the Cartagena Protocol, in 2005 the GON began to require notifications of imports of living modified organisms (LMO) and risk analyses for such imports.

On August 13, 2003 an executive degree was published in the *La Gaceta* 152 requiring risk analyses on genetically modified organisms (GMOs). However, no commission to perform risk analysis was formed until July 23, 2004, when the CONARGEN was named and sworn into office by former President Bolaños. The Chief Director of the General Direction for Animal and Plant Health Protection (DGPSA) of the Ministry of Agriculture and Forestry (MAGFOR) serves as president of the eight-member commission. Other members include officials from the Nicaraguan Institute for Agricultural Technology, the Ministry of Environment and Natural Resources, the Ministry of Health, the Ministry of Industry Development and Commerce, the National Autonomous University of Nicaragua in León, the National Agrarian University, and the Central American University in Managua. Various Ministries and institutions nominate the members of the CONARGEN, who then must be approved by the President. The CONARGEN is attached to MAGFOR through DGPSA, which also provides administrative support.

With the creation of the CONARGEN, the legal framework for the import, use and handling of GMOs outlined by Law 291, Basic Law of Animal Safety and Plant Health, as implemented by Decree 59-2003, entered into force. Importers of a biotechnology product are required to request a risk analysis of an event(s) prior to its importation for the first time. The CONARGEN does not have the technical capability to test if a product is transgenic or not, but it is responsible for reviewing the pertinent information presented by importers for the risk analysis. Based on this information, the CONARGEN makes a recommendation to the Minister of Agriculture and Forestry on whether to permit or deny the import of a biotechnology variety. The Minister makes the final decision. At present, yellow corn for animal feed (events approved in the United States) is the only biotechnology commodity that has been subjected to risk analyses.

The specific requirements to request approval of a biotechnology variety are as follows. The petitioner is required to submit the following information to the CONARGEN for biotechnology products for confined used, development of field tests, crop evaluations, seed multiplication, production or importation for the first time for direct consumption, and/or transformation.

1. General Information

1.1 Name, home address, telephone number of the company's legal representative or requesting institution.

1.2 Scientific and common names and any other designations used to identify recipient and vector agents involved in the production of each GMO.

1.3 Name, address and phone number of the person (s) who produced/processed or provided the GMO.

2. Requirements for transportation and/or importation of GMOs

2.1 Description of the packing used to transport the GMO.

2.2 Quantitative description of the GMO to be transported, proposed transportation and/or importation schedule.

2.3 Transportation route of the GMO, including a description of the country of origin, port of entry, proposed intermediate and final destinations.

2.4 Description of the procedures and biosafety measures to prevent the escape and propagation of the GMO.

Note: If the GMO is not imported or transported within Nicaragua, the requirements listed above will not apply.

3. Specific Information regarding the GMO

3.1 Objective and purpose for importing the GMO.

3.2 Characteristics of the organism from which the GMO derives.

3.3 Pertinent biological, physiological, genetic and environmental characteristics of the recipient organism including:

3.3.1 Name and identity of the organism.

3.3.2 Pathogenic, toxic and allergenic action.

3.3.3 Natural habitat and origin source and/or diversity of the organism, its distribution and function in the environment.

3.3.4 Mechanisms used by the organism to survive, multiply and spread in the environment.

3.3.5 Transfer channels of genetic material to other organisms. Products of plant origin should include the following information: lifecycle with special emphasis on auto crossbreeding, pollination, habitat, wild species and their distribution, mechanisms and frequency of auto crossbreeding with members of the same specie.

3.4 Description of the donor organism; recipient and vector organism, including pathogenic, toxic and allergenic characteristics; country and location where the GMO was collected, developed or produced; and the legal condition of the GMO in the country of origin.

3.5 Description of the actual or anticipated modification granted by the genetic material, incorporated in the GMO (attach maps of this genetic construction). Explain how this genetic modification differs from the unmodified organism. The following elements should be compared to the organism from which the GMO originated:

3.5.1 Pathogenic, toxic and allergenic action for humans and other organisms.
3.5.2 Survival capacity, persistence, competitiveness and transmission into the environment or other pertinent interactions.

3.5.3 Transfer capacity of genetic material and potential transmission channels.

3.5.4 Methods for detecting the organism in the environment and the transfer of the donated nucleic acid.

3.5.5 Characterization of the product or products from the inserted gene (s), and as they originate, stability of the genetic modification.

3.5.6 Detailed description of the molecular biology of the donor-recipient-vector system that sustains the origin of the GMO.

3.5.7 Evaluation of the potential impact on the agricultural environment that could result from releasing the GMO.

3.5.8 Detailed proposed experimental design for releasing the GMO into the environment and production system.

3.5.9 Total quantity of the GMO to be released and to be used for each experiment, if more than one experiment is to be established. Present a calendar indicating the agricultural practices and proposed experiments.

3.5.10 Present a map showing the geographic location of the experiment considering the following:

i) When many genetic constructions are being tested in different sites, indicate which constructions are to be tested at which site.
ii) When several experiments are applied in the same site, indicate the specific location for each experiment.
iii) Describe the former use of the surrounding land and actual location of experiments. For GMOs of plant origin, include a list and description of wild and domestic species genetically related to the GMO that could become recipient of transgenic pollen.
iv) Specify dimensions and experimental area (excluding edges and rows of non-GMO material), description of places for GMO distribution such as greenhouses, laboratories, and growing chambers.
v) Specify procedures and biosafety measures to prevent contamination, escape and propagation of the GMO.
vi) Detailed description of the proposed method for final propagation of the GMO at the end of the experiment including final disposal and cleaning of other materials that were in close proximity with the GMO during the experiment.

4. Additional Specific Information for Confined Use

4.1 Number and volume of the organisms to be used.

4.2 Size of the operation.

4.3 Proposed confinement measures including the verification of their functioning.

4.4 Training and supervision of staff performing assigned duties.

4.5 Waste disposal control plans.

4.6 Unforeseen accident/event control plans.

5. Information for releasing the GMO into the environment.

Certification extended by the exporter's country of origin authorizing the release of the GMO into the environment must be presented to the Chief Director of DGPSA for subsequent risk analysis.

USDA and MAGFOR have negotiated an agreement related to Article 24 of the Cartagena Protocol on the transboundary movement of LMO for food, feed or for processing. This agreement entered into force on February 18, 2005. The arrangement articulates a practical definition for LMO- and non-LMO shipments

for purposes of applying the "may contain" documentation requirement, and recognizes that non-LMO shipments must be defined in a contract as having 95 percent or greater non-LMO content.

At present, the CONARGEN has conducted risk analyses for all genetic events authorized by the United States for yellow corn for purposes of processing and for animal feed only. Risk analyses for human food use have not been requested.

Importers have not asked the CONARGEN to develop risk analysis for any other genetically modified crops besides yellow corn. Legislation allows for field-testing of biotechnology crops after the required risk analysis, but field trials of a biotech crop have never been conducted. Coexistence between biotechnology and non-biotechnology crops has not been reported.

In November 2005, an inter-institutional group overcame a wide range of points of view concerning products derived from biotechnology to reach a consensus on a compromise, science-based biosafety bill. After the biosafety bill was submitted to the National Assembly, some CONARGEN members and Nicaraguan biotechnology experts were involved in a consultative process with the Health Commission of the National Assembly. With presidential elections in November 2006, political and economic matters distracted the attention of the National Assembly. In June 2007, the Health Commission called again some members of the inter-institutional group for consultations on the bill. It appears that the Health Commission has regained interest in the bill; however, the chances of its passage are uncertain.

In June 2007, concurrent to the consultations between the Health Commission and members of the inter-institutional group, the current Administration submitted to the National Assembly a bill on Sovereignty, Food Security and Nutrition. The bill bans donations of biotechnology products, promotes producer participation in commercialization of agricultural products, and proposes the creation of a National Commission for Sovereignty, Food Security and Nutrition presided by the President to direct the formulation, approval, implementation, follow up and evaluation of policies and plans on food security. The bill has not moved forward and is still being discussed. According to some members of Parliament, this bill restricts food donations and establishes a framework for farmers to produce under specific guidelines. The chances of passing the bill on Sovereignty, Food Security and Nutrition are uncertain.

SECTION IV MARKETING ISSUES

At present there is no labeling regulation for food or feed containing GMOs. Therefore, threshold labeling percentages for both intended and adventitious presence of GMOs have not been established. There is no law or regulation governing the use of labeling terms such as "biotech-free," "non-biotech," or "non-GMO."

SECTION V CAPACITY BUILDING AND OUTREACH

In September 2006, selected members of the CONARGEN and Nicaraguan biotechnology experts attended a biotechnology course at Michigan State University (MSU). This course provided guidance and useful information to Nicaraguan participants, who have been advising legislators on biotechnology matters. This training enhanced the participants' ability to understand the U.S. regulatory framework on agricultural biotechnology, to make appropriate decisions about risk and risk management, and to maintain access for U.S. biotechnology products in Nicaragua. Ministries with representation in the CONARGEN benefited from the science-based education conveyed at the MSU course. In the second semester of 2007, some CONARGEN members and two Nicaraguan biotechnology scientists are scheduled to attend another biotechnology training in the US.

The Nicaraguan population including the media and legislators has limited understanding of biotechnology products. Generally, consumers associate biotechnology exclusively to GMOs. The lack of information reduces the level of acceptance of biotechnology products among consumers and could become a limiting factor in the market.

SECTION VI COUNTRY NEEDS

Members of the CONARGEN are well educated in different agricultural fields and are inclined to base their decisions on factual scientific data. However, they lack the proper infrastructure to conduct detailed risk analysis. The CONARGEN has expressed interest in developing a laboratory and office space that would help to develop their work.

U.S. companies that produce biotechnology products, including planting seed varieties that would be suitable for Nicaraguan conditions, may wish to consider working with a local representative to initiate regulatory review of new-to-market product(s) and, at the appropriate time, start marketing the product to agricultural and livestock producers and to processors. U.S. exporters should take into the account the need to educate Nicaraguan users and consumers as part of their marketing strategy.